IV. REMARKS

The Office Action dated January 28, 2008, has been received and carefully noted. The amendments made herein and the following remarks are submitted as a full and complete response thereto.

Claims 7-12 are pending. Claims 7-10 were withdrawn from consideration by the Examiner.

The abstract and drawings have been amended in accordance with the Examiner's requirement. Applicants submit that no new matter has been added.

Drawings

The Examiner has required new corrected drawings in compliance with 37 CFR § 1.121(d), because Figure 6 is not in English. Applicants have submitted a corrected Figure 6, which is in English.

Specification

The Examiner has objected to the abstract as being generally narrative and indefinite. Applicants have submitted a replacement abstract.

Objection

Claim 11 has been objected to because the word "granulates" is listed twice in line 3 of the claim. Applicants respectfully disagree with this objection and submit that the listing of the word "granulate" is not an error. Applicants submit that "base

granulates" and "granulates that contain an active substance" refer to two separate types of granulates. Therefore, Applicants respectfully request reconsideration and withdrawal of the rejection to claim 11.

Rejections under 35 U.S.C. § 103

1. *Yang et al.*

Claim 11 has been rejected under 35 U.S.C. § 103(a) over Yang et al. (U.S. Patent No. 4,740,376). Applicants traverse the rejection.

Claim 11 is directed to a "method of producing solid pharmaceutical preparations, comprising using the polyvinylacetates of claim 10 as a binder, alone or in combination with other binders, in base granulates or granulates that contain an active substance, wherein the polyvinylacetates are used in a solution with solvent or as a solid powder." Applicants submit that the polyvinylacetates of claim 10 have the following claimed properties: mean molecular weight between 10,000 and 40,000 Daltons, remnant monomer content of less than 2 ppm by weight, water content less than 1.5% by weight, total acidity referred to acetic acid less than 0.5% by weight, peroxide content of 0.0%, and glass transition temperature of 35°C to 39°C.

Applicants submit that Yang et al. does not teach or suggest the presently claimed invention. Applicants respectfully submit that although Yang et al. discloses pharmaceutical compositions that are produced in a melt, the Examiner improperly assumes that any water is evaporated and that the water content of the polyvinylacetate (PVAc) would obviously be less than 1.5%. Applicants further submit that the

polyvinylacetates of the presently claimed invention are not restricted to those which have to be molten. In addition, Applicants submit that the Examiner incorrectly assumes that the PVAc disclosed in Yang et al. contain very low quantities of impurities and contaminants, as Yang et al. provides no disclosure of this. In contrast, the presently claimed application describes toxicological studies that support the innocuousness of the product obtained by the procedure. The importance and difficulty of industrially obtaining of high purity PVAc for the intended use is discussed below.

Applicants submit that the use of polyvinylacetate and copolymers of vinyl acetate- vinyl alcohol according to the presently claimed invention, as a sole or main product in drug delivery matrixes or as a binder in both cases for tablet production, results in high purity. Applicants submit that the purity of the products is of great importance regarding to remnant monomer content, not only from the point of view of toxicity of the monomer itself, but also because this very reactive substance can interact with the many possible active substances or excipients in the solid final pharmaceutical forms in an unpredictable way (see page 9, 15-28 of the specification).

Applicants submit that the claimed method is characterized by the use of a vacuum and slow stirring at a certain temperature, which is an important aspect of the purification procedure. Applicants submit that the certain temperature (between 80°C and 140°C) is high enough to allow for a viscosity of the polymeric mass that is not extremely high, and which does not induce thermal or hydrolytic decomposition of the product. Applicants note that if the molecular weight of a polyvinylacetate is higher than 40,000 daltons, the viscosity at the highest temperature by which there is still no

decomposition of the polymer, would be too high to allow for stirring of the polymer mass (see specification, page 10, lines 12-30). Applicants submit that this is very important because the monomer and water are retained very strongly within the polymer due to similar polarity and affinity. Applicants submit that traces of monomer or water are very difficult to eliminate, since the viscosity rises, as discussed in the specification on page 9, lines 15-28. Applicants submit that the higher the viscosity, the slower the diffusion of water and monomer out of the polymeric mass. The drying, for example, with a static procedure in vacuum ovens is too slow and requires large and very expensive equipment. This is determined by the fact that the width of the polymer layer on the trays should be small, because otherwise the wet inflated polymer would overflow the trays at the beginning of the drying process. Applicants submit that if the depth of the polymer layer is not thin enough, then the drying process under vacuum and high temperature would last an extended period of time, for example, many days. Applicants submit that if the depth of the layer is too thin, then the process is not sufficiently intensive.

For example, Applicants note that 70 kg of polyvinylacetates with mean molecular masses under 40,000 daltons can be stirred under vacuum to dryness at a stirring velocity of 13 rpm with a 2 hp electric motor in proper equipment within less than 6 hours.

Applicants note that polyvinylacetates having a water content of higher than 1.5% by weight cannot be milled, since it would show plastic properties at room temperature. Applicants submit that the claimed polyvinylacetates and method overcome the difficulty

of milling in a way that permits their safe use in solid form (due to their high purity) in the pharmaceutical industry and allows for storage for relatively long periods at room temperature without agglomeration of the powders. Based on the claimed method, it is possible to obtain base granulates or granulates without the need to dissolve the polymers or copolymers prior to use.

Further, Applicants submit that the mere similarity in molecular weight between the compound disclosed in Yang et al. and the presently claimed invention does not mean that the compounds would necessarily have the other claimed properties.

For at least the reasons stated above, Applicants respectfully request reconsideration and withdrawal of the rejection of claim 11 under 35 U.S.C. § 103(a) over Yang et al.

2. *Sa*

Claim 11 was rejected under 35 U.S.C. § 103(a) over Sa (Drug Development and Industrial Pharmacy, 17(6), 893-900 (1991)). Applicants traverse the rejection.

Claim 11 and the features of the presently claimed invention have been discussed above.

Applicants submit that Sa does not teach or suggest the presently claimed invention. For example, Applicants submit that the Examiner improperly assumes that the polyvinylacetate described in Sa has a low water content since the microspheres of Sa, which contain theophylline and polyvinylacetate, were dried in a vacuum desiccator. Applicants submit that this may be the case, but the described procedure is not an

industrial one and is not suited for purifying a polymer whose use is not restricted to the production of microspheres. Applicants submit that the high purity of the presently claimed polyvinylacetates cannot be achieved according to the method disclosed in Sa.

Further, Applicants submit that the mere similarity in molecular weight between the compound disclosed in Sa and the presently claimed invention does not mean that the compounds would necessarily have the same claimed properties.

For at least the reasons stated above, Applicants respectfully request reconsideration and withdrawal of the rejection of claim 11 over Sa.

3. *Yang et al., in view of Sa*

Claims 11-12 were rejected under 35 U.S.C. § 103(a) over Yang et al., in view of Sa. Applicants traverse the rejection.

As discussed above, Applicants submit that the presently claimed invention is not taught by Yang et al. and Sa. Applicants submit that the deficiencies of Yang et al. are not cured by Sa, and neither reference teaches the polyvinylacetates of the presently claimed invention.

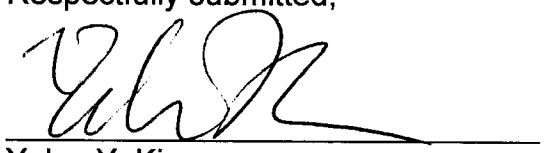
Therefore, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 11-12 under 35 U.S.C. § 103(a) over Yang et al., in view of Sa.

V. CONCLUSION

Applicants respectfully submit that this application is in condition for allowance and such action is earnestly solicited. If the Examiner believes that anything further is desirable in order to place this application in even better condition for allowance, the Examiner is invited to contact Applicants' undersigned representative at the telephone number listed below to schedule a personal or telephone interview to discuss any remaining issues.

In the event this response is not timely filed, the Applicants hereby petition for an appropriate extension of time. The fee for this extension, along with any other additional fees which may be required with respect to this response, may be charged to Deposit Account No. **01-2300**, referencing Attorney Docket No. **024273-00001**.

Respectfully submitted,



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